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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,275	08/22/2001	Gerardo Castillo	PROTEO.P03	1974

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 09/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/938,275	Applicant(s) CASTILLO ET AL.	
	Examiner Olga N. Chernyshev	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,11,12,15 and 17-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,11,12,15 and 17-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 19, 2004 has been entered.

Response to Amendment

2. Claims 1, 4, 5, 11, 12, 15 and 19 have been amended, claims 2 and 3 have been cancelled and claims 22-27 have been added as requested in the amendment filed on July 19, 2004. Claims 1, 4, 5, 11, 12, 15 and 17-27 are pending in the instant application.

Claims 1, 4, 5, 11, 12, 15 and 17-27 are under examination in the instant office action.

3. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. Applicant's arguments filed on July 19, 2004 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Objections

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6. Claims 1 and 15 are objected to because of the following informalities: “administrating” should be “administering”, perhaps. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. Claims 1, 4, 5, 11, 12, 15 and 17-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for inhibiting or reducing beta-amyloid protein fibril formation by addition of laminin *in vitro* and within cell-free system, does not reasonably provide enablement for the full scope of the claimed invention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claims 1, 4, 5, 11, 12, 15 and 17-27 are directed to methods of inhibiting or reducing beta-amyloid protein fibril formation by administration of laminin to a site containing beta-amyloid protein. The instant invention relates to the field of treatment of Alzheimer’s disease, which, according to the state in the art, is considered to be a fatal disease for which no anti-amyloid therapies are currently available (see Cummings J., 2004, New England J. Medicine, vol. 351, pp. 56-67, abstract and page 58, bottom at first column). Note that with regard to establishing the breadth of the claims, the standard under 35 U.S.C. §112, first paragraph, entails the determination of what the claims recite and what the claims mean as a whole. In addition, when analyzing the enablement scope of the claims, the teachings of the specification are to be taken into account because the claims are to be given their broadest reasonable interpretation that is consistent with the specification. As such, the broadest reasonable interpretation of the claimed method is such that it encompasses administration of laminin to a site containing beta-amyloid

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protein, which includes cell-free conditions as well as *in vitro* cell cultures and *in vivo* administration of laminin (see claims 5 and 22, for example). In order to practice the claimed method without undue experimentation and with reasonable expectation of success, a skilled artisan would have to rely on the instant disclosure, as originally filed. However, the information presented in the instant specification is limited to the description of a working hypothesis regarding inhibitory effects of laminin on amyloid fibril formation (see pages 3-5 and 25-28, for example), which is supported by working examples limited to *in vitro* and cell-free binding experiments using beta-amyloid and laminin proteins (pages 28-50, for example). Thus, in view of the lack of teachings and unpredictability of the art set forth earlier in this office action and fully explained in previous office actions of record (see office communications mailed on April 21, 2003 and on March 19, 2004), and also the total absence of the working examples related to *in vivo* conditions, the instant specification is not found to be enabling for the full scope of the claimed method. It would require undue experimentation and making a substantial inventive contribution for the skilled artisan to discover how to practice Applicant's invention commensurate in scope with the instant claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 4, 5, 11, 12, 15 and 17-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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9. Claims 1, 15 and 19 are vague and indefinite for recitation "therapeutically effective amount". Term "therapeutic" has meaning as "pertaining to the healing art". Because claims 1, 15 and 19, as written, encompass cell-free conditions and well as *in vitro* conditions within a cell culture, clinical relevance of the recitation cannot be determined. Clarification is required.
10. Claim 5 recites the limitation "fibrils" (plural) in claim 1. There is insufficient antecedent basis for this limitation in the claim.
11. Claim 11 is vague and ambiguous for recitation "a fragment thereof". It is not clear and cannot be determined from the claim if "a fragment" refers to SEQ ID NO: 3 or to globular domain.
12. Claims 17 and 18 are indefinite for reciting the limitation "body weight" in claim 1. There is insufficient antecedent basis for this limitation in the claim, see reasons of record in section 9 of the instant office action.
13. Claim 22 recites the limitation "beta-amyloid protein disease" in claim 15. There is insufficient antecedent basis for this limitation in the claim.
14. Claims 23 and 24 are indefinite for reciting the limitation "body weight" in claim 15. There is insufficient antecedent basis for this limitation in the claim, see reasons of record in section 9 of the instant office action.
15. Claims 25 and 26 are indefinite for reciting the limitation "body weight" in claim 19. There is insufficient antecedent basis for this limitation in the claim, see reasons of record in section 9 of the instant office action.
16. Claims 4, 12, 20-21 and 27 are indefinite for being dependent from indefinite claims.

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Double Patenting

17. Applicant is advised that should claims 15 and 20 be found allowable, claims 19 and 21 will be objected to under 37 CFR 1.75 as being substantial duplicates thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Applicant is advised that recitation “administering to a site containing beta-amyloid protein” in claim 15 is identical in content to the recitation “administering [...] into any site containing beta-amyloid protein”, therefore, claims 15 and 19, as well as dependent claims 20 and 21, respectively, are directed to the same subject matter.

Conclusion

18. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax

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center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Olga N. Chernyshev, Ph.D.


OLGA N. CHERNYSHEV, PH.D.
PATENT EXAMINER